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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SHANG-REN WU,
ANGEL ALVAREZ, and STEPHEN SIMMONS, JR.

Appeal 2016-000019
Application 11/855,437
Technology Center 1700

Before KAREN M. HASTINGS, GEORGE C. BEST, and
N. WHITNEY WILSON, *Administrative Patent Judges*.

HASTINGS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellants[1] appeal the Examiner's decision finally rejecting claims 1–4, 6–9, 11, 12, 14–19, 21–24, and 26–29 under 35 U.S.C. § 103(a). We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] The real party in interest is stated to be Becton, Dickinson & Co. (Appeal Br. 1).

Claims 1 and 14 are illustrative of the appealed subject matter (paragraphing and emphasis added to highlight key disputed limitations):

1. A chamber for a medical article,

the chamber having an inner surface adapted to sealingly engage an outer surface of a sealing member for a medical article,

wherein the inner surface of the chamber has a coating thereon prepared from a composition comprising an organopolysiloxane, the organopolysiloxane having a viscosity of about 100 to about 100,000 centistokes, the coating being adhered to the inner surface by crosslinking induced by

(1) oxidative treatment for a time period of about 1 second to about 10 minutes; and subsequent

(2) irradiation of about 5 to about 50 kiloGreys with an isotope or electron beam,

wherein the chamber is prepared from cyclic polyolefin.

14. A sealing member for a medical article,

the sealing member having an exterior surface in sliding engagement with an interior surface of a chamber of a medical article and adapted to sealingly engage the interior surface of the chamber,

wherein the exterior surface of the sealing member has a coating thereon prepared from a composition comprising an organopolysiloxane, the organopolysiloxane having a viscosity of about 1,000 to about 500,000 centistokes, the coating being adhered to the exterior surface by crosslinking induced by

(1) oxidative treatment for a time period of about 1 second to about 10 minutes; and subsequently

(2) irradiation of about 5 to about 50 kiloGreys with an isotope or electron beam,

wherein the chamber is prepared from cyclic polyolefin.

(Appeal Br. 37, 39; Claims App.).

The Examiner maintains the following rejections:

(a) claims 14–19, 21, 22, 24, and 28 are rejected under 35 U.S.C. § 103(a) as unpatentable over Lubrecht (US 6,746,430 B2, issued June 8, 2004) (hereinafter "Lubrecht") in view of Williams et al. (US 4,767,414, issued Aug. 30, 1988) (hereinafter "Williams");

(b) claim 29 is rejected under 35 U.S.C. § 103(a) as unpatentable over Lubrecht in view of Williams, and further in view of Reinhard et al. (US 6,065,270, issued May 23, 2000) (hereinafter "Reinhard"); and

(c) claims 1–4, 6–9, 11, 12, 23, 26, and 27 are rejected under 35 U.S.C. § 103(a) as unpatentable over Lubrecht in view of Berg (WO 2004/064901 A2, published Aug. 5, 2004) (hereinafter "Berg"), and further in view of Williams and Reinhard.

Appellants' arguments urging reversal of the obviousness rejections of claims 2–4, 6–9, 11, 12, 15–19, 21–24, 26, and 28 focus on limitations common to independent claims 1 and 14 (Appeal Br. 14, 20). Thus, in the absence of specific arguments for their patentability, dependent claims 2–4, 6–9, 11, 12, 23, and 26 stand or fall with claim 1; and dependent claims 15–19, 21, 22, 24, and 28 stand or fall with claim 14. 37 C.F.R. § 41.37(c)(1)(iv).

ANALYSIS

Upon consideration of the evidence on this record and each of Appellants' contentions, we find that the preponderance of evidence supports the Examiner's conclusion that independent claims 1 and 14; all of their respective dependent claims; and independent claims 27 and 29, are unpatentable over the applied prior art and that Appellants have failed to

show that the Examiner erred reversibly. We sustain the Examiner's § 103 rejections, listed in (a)–(c) above, of all the appealed claims for essentially the reasons set out by the Examiner in the Answer.

We add the following primarily for emphasis.

Rejections (a) and (b)

Appellants' main argument is that "one of ordinary skill in the art would have no motivation, reason, or suggestion to treat the sealing member of Lubrecht with ionizing plasma as disclosed by Williams" (Appeal Br. 13). Appellants argue that because Lubrecht teaches that radiation treatment provides crosslinking between silicone molecules and a syringe stopper, the ordinary skilled artisan would infer that Williams' "subsequent ionizing [i.e., oxidation] treatment would not be effective to induce appreciable further crosslinking" (*id.* at 13 (citing Lubrecht 3:9–12; 1:66–2:4)). According to Appellants, "it would be counterintuitive to duplicate [Lubrecht's] crosslinking effect and adherence to the sealing member already achieved by [Williams'] first process" (Reply Br. 3).

Appellants' arguments are not persuasive because they do not fully address the inferences of the references that are presented on this record for our review. As set forth in the Answer, the Examiner supports the prima facie case of obviousness based on the combined teachings of Lubrecht and Williams, either with or without Reinhard (Ans. 3–11; 16–19). Appellants' arguments, however, fail to consider this prior art as a whole, and do not directly address the Examiner's position (*e.g.*, *id.*). *See, e.g.*, *In re Preda*, 401 F.2d 825, 826 (CCPA 1968) (it is well established that in evaluating references it is proper to take into account not only the specific teachings of

the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom).

Appellants have not sufficiently refuted and, thus, have not shown reversible error in the Examiner's determination that it would have been prima facie obvious to combine the known method of crosslinking lubricating silicone on a sealing member's exterior surface by irradiation, as suggested by Lubrecht, after initially crosslinking the same substance onto the same surface using an oxidative plasma treatment, as suggested by Williams, to enhance lubricant stability and its resistance to migration (*e.g.*, Ans. 17).

Appellants have also not provided persuasive technical reasons or evidence that demonstrate reversible error in the Examiner's determination that it would have been prima facie obvious to combine Lubrecht's and Williams' teachings (*e.g.*, *id.* at 3–11; 16–19), to achieve, with the use of no more than ordinary creativity, the known desirable results of increased lubricant stability and migration resistance, while reducing the known problem of sudden separation of stationary surfaces in contact (*see generally id.*; Appeal Br.; Reply Br.). *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). Therefore, Appellants' arguments that it would be counterintuitive to duplicate Lubrecht's crosslinking effect and adherence to the sealing member already achieved by Williams are unpersuasive. The record evidence provides that it was known to the ordinary skilled artisan that crosslinking silicone lubricant to sealing member surfaces may be induced by irradiation and oxidative plasma

treatment, and that such plasma treatment would enhance lubricant stability and migration resistance (*see* Final Act. 4; Ans. 3).

Appellants argue that the Examiner's position is erroneous because "there is no guidance to suggest whether one would subject the object to irradiation first, or plasma first" (Appeal Br. 14). Appellants further argue that the ordinary skilled artisan "could apply a plasma treatment after radiation; however, the resulting product would need to be sterilized subsequently, adding another processing step; and increased cost" (*id.*). Thus, Appellants conclude that the applied prior art "provide[s] no guidance to subject the sealing member to oxidative treatment first, then subsequently to irradiation" (*id.*).

It is, however, well established that when claimed and prior art products are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). This is true whether the rejection is under 35 U.S.C. § 102 (anticipation) or 35 U.S.C. § 103 (obviousness), and is based on the fact that the PTO is not in a position to manufacture products or to obtain and compare prior art products. *Id.*

Appellants' arguments are not persuasive because the Examiner has explained why both Lubrecht's process of irradiating a lubricated sealing member with cobalt radiation at a target dose of 2.5 to 4.0 Mrads and Williams' method of treating a syringe coated with polydialkylsiloxane with ionizing plasma is substantially similar to the process described in Appellants' claims (Ans. 4–5 (citing Lubrecht ¶¶ 3:3–10; Williams 2:34–65; 4:20–36)). Placing the burden on Appellants is appropriate under these

circumstances. *See Best*, 562 F.2d at 1255. Appellants have not met this burden for the reasons set forth in the Examiner's Answer.

Appellants filed four Rule 132 Declarations of named inventor Dr. Shang-Ren Wu to rebut the Examiner's prima facie case of obviousness. Appellants filed the First Declaration to "demonstrate the criticality of treating syringes or stoppers for medical articles with oxidative treatment followed by irradiation" (Appeal Br. 21). Appellants filed the Second Declaration and Third Declaration to provide additional evidence of nonobviousness and to refute the Examiner's findings that data submitted to demonstrate criticality of the claimed invention did not support the scope of the claims (*id.* at 24, 26). Appellants filed the Fourth Declaration to refute the Examiner's position that the results of Dr. Wu's experiments do not prove that irradiation crosslinks siloxane to the sealing member (*id.* at 30).

Appellants' assertion that the four Declarations of Dr. Wu and the test data disclosed in the originally filed application provide both:
(i) unexpected results demonstrating the criticality of using irradiation after oxidative plasma treatment (*e.g.*, Appeal Br. 26, 28; Reply Br. 5), and
(ii) sufficient evidence to rebut the Examiner's prima facie case of obviousness (*e.g.*, *id.* at21, 35), is unpersuasive.

It is well settled that the burden of establishing unexpected results rests on the party asserting them. *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). In this instance, Appellants have not provided the required side-by-side comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims, and explained why the results would have been unexpected by one of ordinary skill in the art. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991); *In re De Blauwe*,

736 F.2d 699, 705 (Fed. Cir. 1984); *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983). As the Examiner notes, Dr. Wu's submitted data is not commensurate in scope with the scope of the claims:

> No data is provided for organopolysiloxane having any viscosity other than 12.5k cst (barrel) and 100k cst (stopper), while claims 1 and 14 broadly recite a viscosity of about 100 to about 100,000 cst for the barrel and about 1,000 to about 500,000 cst for the stopper.
>
> No data is provided for any amount of plasma treatment other than 3–10 seconds, while claims 1 and 14 broadly [recite] 1 second to 10 minutes.
>
> No data is provided for any type of oxidative treatment other than Ar plasma, He:Ar, Ar:O_2, He:O_2 and He:Ar, while claims 1 and 14 broadly recite any type of oxidative treatment.
>
> No data is provided for any type of plasma treatment other than Ar plasma, He:Ar, Ar: O_2, He:O_2 and He:Ar, while claim 21 broadly recites any type of plasma treatment.
>
> Additionally, it is noted that for some of the data, for example the viscosity of the organopolysiloxane on the barrel and on the stopper, only one data point is provided (12.5k cst (barrel) and 100k cst (stopper)).

(Ans. 36–37).

Appellants argue that: (i) "the Third Declaration of Dr. Wu clearly explains why one of ordinary skill in the art would be able to determine the trend in the submitted data to support the assertion of unexpected results" (Reply Br. 8) and (ii) the Examiner objects to Dr. Wu's evidence without providing evidence to the contrary (Appeal Br. 35).

Appellants' arguments, however, are not convincing. As the Examiner found, Dr. Wu's explanation "is merely a conclusory statement and no evidence (i.e. data) is provided to support this assertion" (Ans. 24). Furthermore, the ordinary skilled artisan would not be able to reasonably

discern a trend from data that provides a single data point for viscosity of the organopolysiloxane on the barrel and on the stopper. Appellants' second assertion, moreover, impermissibly places a burden on the Examiner to prove that the prior art products necessarily or inherently possess the characteristics of Appellants' claimed product. *See Best*, 562 F.2d at 1255.

Appellants, thus, have not shown reversible error in the Examiner's finding that the experimental data set forth in the Specification (*see, e.g.*, Ans. 23) and the four Rule 132 Declarations of Dr. Wu are not commensurate in scope with the scope of the claims (*see, id.* at 21–32; 36–37). For these reasons, Appellants have not adequately demonstrated criticality regarding the order of steps. Therefore, Appellants' evidence is not persuasive evidence of the nonobviousness of independent claims 14 and 29.

Thus, we affirm the rejections of claims 14–19, 21, 22, 24, 28, and 29.

Rejection (c)

The Examiner determines that it would have been obvious to apply silicone lubricant to Berg's chamber surface constructed of Reinhard's cyclic polyolefin, then subject it to Williams' oxidative treatment, followed by treatment with Lubrecht's irradiation, in order to induce crosslinking within the chamber surface (Ans. 12–16). The Examiner further determines that one of ordinary skill in the art would have found it obvious to apply such oxidative treatment, followed by irradiation, to prevent migration of the lubricant into the medicament (*id.* at 14).

Appellants' main argument is that Lubrecht teaches away from the present invention because "Lubrecht specifically states that the 'prelubrication of the plastic material during the plastic compounding

procedure ***effectively eliminates*** the possibility for the lubricant to become deposited in the medicament'" (Reply Br. 4 (citing Lubrecht 3:27–33 (emphasis added); *see also* Appeal Br. 19–20). Appellants further argue that "because the prelubricated plastic material ***effectively eliminates*** migration of the lubricant into the medicament as well as the need to apply additional lubricant to the inside of the chamber, Lubrecht teaches away from post-treatment of the chamber" (Reply Br. 4).

Whether a reference teaches away from a claimed invention is a question of fact. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005). For a reference to "teach away," it must criticize, discredit, or otherwise discourage the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Appellants' arguments are not persuasive because they fail to identify any teaching in the applied prior art that criticizes, discredits, or discourages oxidative treatment, followed by irradiation treatment, of a chamber's silicone lubricated inner surface as claimed. Therefore, we are not persuaded by Appellants' arguments that Lubrecht teaches away from independent claims 1 and 27.[2]

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[2] We note that Appellants' claims are directed to an apparatus defined by processing steps. In other words, the instant claims are written in a product-by-process format. In such circumstances, we gauge "the patentability of the products defined by the claims, rather than the processes for making them, . . . in light of the prior art." *In re Wertheim*, 541 F.2d 257, 271 (CCPA 1976); *see also In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself"). As the Examiner finds, the chamber and/or sealing member surfaces disclosed in the applied prior art of Lubrecht, Williams and Berg each adhere silicone

Furthermore, for the reasons set forth above, Appellants have not shown reversible error in the Examiner's finding that the experimental data set forth in the Specification (*see, e.g.*, Ans. 23) and the four Rule 132 Declarations of Dr. Wu are not commensurate in scope with the scope of the claims (*see, id.* at 21–32; 36–37). In other words, Appellants have not sufficiently demonstrated the criticality of the order of steps. Therefore, Appellants have not submitted persuasive evidence of the nonobviousness of independent claims 1 and 27.

We, therefore, affirm the rejection of claims 1–4, 6–9, 11, 12, 23, 26, and 27.

DECISION

The Examiner's § 103 rejections are affirmed.

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lubricant (*see generally* Ans. 3–16). Appellants do not contest these findings (*see, e.g.*, Appeal Br. 13; Reply Br. 3, 12, 16). Indeed, Williams discloses that, in a preferred embodiment, "the [silicone] lubricant is . . . applied to the surfaces of a syringe barrel *and* associated syringe stopper prior to the plasma treatment" (Williams 2:47–50 (emphasis added)). In the absence of persuasive evidence or arguments that Williams' apparatus could not adhere silicone lubricant without modification, the teachings of Lubrecht and Berg are cumulative. *See, e.g., Wertheim*, 541 F.2d at 271; *see also Thorpe*, 777 F.2d at 697. Appellants have not identified any structural differences in the claimed sealing member or chamber compared to Williams' sealing member and chamber. Rather, they have merely argued that the combined teachings of the applied prior art do not teach the claimed processing steps.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED